



K100905

JUN - 2 2010

May 27, 2010

510(k) Summary as required by section 807.92

Proprietary Name: *HydroFix™ Vaso Shield*
Common Name: Vessel Guard or Cover
Classification Name: Intracardiac patch or pledget made of polypropylene, polyethylene terephthalate, or polytetrafluoroethylene. (per 21 CFR 870.3470)
Device Class: Class II
Product Code: OMR
Classification Panel: Cardiovascular Devices
Establishment Registration: 3006731846
Contact Person: Sally Thorsen
MiMedx Group, Inc.
811 Livingston Court SE, Suite B
Marietta, GA 30067
(678) 384-6720
Fax 678-384-6741
sthorsen@mimedx.com

Performance Standards:

Performance standards do not currently exist for these devices.

Device Description:

The MiMedx *HydroFix™ Vaso Shield* is a flexible sheet of polyvinyl alcohol (PVA) material provided in various dimensions. There are no holes or perforations. There are no markings on either side of the sheet, raised (embossed) or printed. The sheet is provided sterile and hydrated.

Indications for Use:

The MiMedx *HydroFix™ Vaso Shield* is indicated as a cover for vessels during anterior vertebral surgery.



May 5, 2010

Substantially Equivalent Devices:

The following devices as substantially equivalent predicate devices listed below.

K090022 *Paradis Vaso Shield*™

K093551 *Paradis Vaso Shield*™

The MiMedx *HydroFix*™ *Vaso Shield* was shown to be substantially equivalent to previously cleared device and has the same indications for use, design, function, and/or materials.

Brief Comparison Summary:

To demonstrate substantial equivalence of the MiMedx *HydroFix*™ *Vaso Shield* to the predicate devices, technological characteristics and performance criterion were evaluated using *in vitro* and *in vivo* testing as indicated below:

***In Vitro* Testing**

- Suture pull out

The results from this test demonstrate that the technological characteristics and performance criteria of the MiMedx *HydroFix*™ *Vaso Shield* are comparable to the predicate devices and that it can perform in a manner equivalent to devices currently on the market for the same intended use.

***In Vivo* Testing**

To assess the performance of the MiMedx *HydroFix*™ *Vaso Shield*, an *in vivo* study was conducted in a porcine model to evaluate the following attributes:

- reflectivity of light from the surgical sheet
- edge sharpness
- ability to suture to tissue
- ability to secure to tissue
- ability to cut the sheet

The results of this study show that the MiMedx *HydroFix*™ *Vaso Shield* are comparable to the predicate devices and that it can perform in a manner equivalent to devices currently on the market for the same intended use.

Conclusion:

The sponsor believes that the data and information presented in this 510(k) application, including *in vitro* and *in vivo* testing, and numerous device similarities support a determination of substantial equivalence, and therefore market clearance of the MiMedx *HydroFix*™ *Vaso Shield* through this 510(k) Premarket Notification.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

JUN - 2 2010

MiMedx Group, Inc.

c/o Ms. Sally Thorsen
Director, Regulatory Affairs and Quality Assurance
811 Livingston Court SE, Suite B
Marietta, GA 30067

Re: K100905

MiMedx HydroFix™ Vaso Shield

Regulation Number: 21 CFR 870.3470

Regulation Name: Intracardiac patch or pledget made of polypropylene, polyethylene
terephthalate or polytetrafluoroethylene

Regulatory Class: Class II

Product Code: OMR

Dated: May 5, 2010

Received: May 6, 2010

Dear Ms. Thorsen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

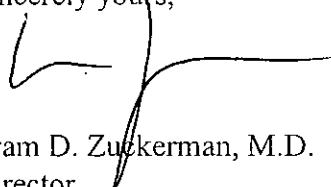
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100905

Device Name: *HydroFix™ Vaso Shield*

The MiMedx Group, Inc. *HydroFix™ Vaso Shield* is indicated as a cover for vessels during anterior vertebral surgery.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K100905